

JUN 27 2002

K021535

**Bayer Diagnostics**  
**ASC:180 and ADVIA Centaur Insulin Calibrator**  
**Section 2: Summary of Safety and Effectiveness**

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

**1. Submitter Information**

Contact person: Kenneth T. Edds Ph.D.  
Address: Bayer Diagnostics Corporation  
511 Benedict Ave.  
Tarrytown, NY 10591  
Phone: (914) 524-2446  
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Date Summary Prepared: April 29, 2002

**2. Device Information**

Proprietary Name: ADVIA Centaur and ACS:180 Insulin  
Calibrator  
Common Name: Calibrator for immunoassay analyte  
Classification Name: Calibrator §862.1150.  
Class: Class II  
CFR: 862.1150  
Product Code: 75 JIT

**3. Predicate Device Information**

Name: ST AIA-PACK IRI Calibrator Set  
Manufacturer: TOSOH Corporation  
TOSOH Kyobashi Building  
3-2-4 Kyobashi, Chuo-ku, Tokyo 104-0031,  
Japan  
Phone: +81-(3)-3275-1221  
Fax: +81-(3)-3275-1214  
510(k) Number: K903628

#### 4. Device Description

The ACS:180 and ADVIA Centaur Insulin Calibrator is a casein buffered solution containing potassium thiocyanate and sodium azide.

#### 5. Statement of Intended Use

For use in calibrating the ADVIA Centaur and ACS:180 Insulin immunoassays on the automated analyzers marketed by Bayer Corporation.

#### 6. Summary of Technological Characteristics

The ADVIA Centaur and ACS:180 Insulin Calibrators are similar to the TOSOH Corporation AIA-PACK IRI Calibrator Set (K903628) in the indications for use, and reference method for standardization, WHO 66/304. In the ACS:180 and ADVIA Centaur Insulin calibrator a buffer base is used to replace the human serum base used in the TOSOH Corporation AIA-PACK IRI Calibrator Set.

#### 7. Accuracy and Precision

The commercial control dose data represented in this document was generated using the calibrators for each respective insulin immunoassay.

Substantial equivalence to the AIA-PACK IRI Calibrator Set is based on comparison of the control accuracy and precision of the ADVIA Centaur and ACS:180 to the predicate device.

System	Sample ID	Mean	Within Run %CV	Total %CV	% Recovery vs TOSOH
AIA TOSOH	Level 1	14.63	2.7	3.6	
	Level 2	48.71	2.1	2.9	
	Level 3	121.27	2.1	3.0	
ADVIA Centaur	Level 1	14.78	2.9	3.1	101.0
	Level 2	42.85	2.8	2.7	88.0
	Level 3	121.82	2.6	3.3	100.5
ACS:180	Level 1	14.26	4.8	8.1	97.5
	Level 2	43.79	3.9	7.6	89.9
	Level 3	120.58	3.1	5.9	99.4



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Kenneth T. Edds, Ph.D.  
Manager, Regulatory Affairs  
Bayer Diagnostics  
511 Benedict Avenue  
Tarrytown, NY 10591-5097

JUN 27 2002

Re: k021535  
Trade/Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur Insulin Calibrator  
Regulation Number: 21 CFR 862.1150  
Regulation Name: Calibrator  
Regulatory Class: Class II  
Product Code: JIT  
Dated: May 3, 2002  
Received: May 10, 2002

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory-Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K021535

Device Name: Bayer Diagnostics ACS:180 and ADVIA Centaur Insulin Calibrator

**Indications for Use:**

The ACS:180 and ADVIA Centaur Insulin calibrators are used for calibrating the ACS:180 and ADVIA Centaur Insulin Immunoassays.

The ACS:180 and ADVIA Centaur Insulin are sandwich, chemiluminescence immunoassay for the quantitative determination of Insulin in human serum for use on the automated analyzer marketed by Bayer Corporation. The ACS:180 and ADVIA Centaur Insulin Immunoassays can be used to aid in the diagnosis and treatment of diabetes mellitus and hypoglycemia.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Jean Coops  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K021535